HOUSE BILL 821
By Hood

SENATE BILL 297

By Ketron

AN ACT to amend Tennessee Code Annotated, Title 38; Title 53 and Title 63, relative to the safeguarding and monitoring of prescription drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, Chapter 10, is amended by adding the following as a new part 4:

53-10-401.

(a) As used in this part, unless the context otherwise requires:

(1) "Dispenser" means a person who delivers a Schedule II-V controlled substance to the ultimate user, but does not include:

(A) A licensed hospital pharmacy that distributes such substances for the purpose of inpatient hospital care or the dispensing of prescriptions for controlled substances at the time of discharge from such a facility; or

(B) A wholesale distributor of a Schedule II-V controlled substance;

(2) "Diversion investigation unit" means the diversion investigation unit of the Tennessee bureau of investigation.

(3) "Facility" means a health care provider, registered with the department of public health, which employs more than one (1) person who can prescribe drugs;

(4) "Official prescription forms" means the serialized and tamper-resistant prescription pads; and

(5) "Patient" means the person or animal who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

(b)

(1) The board of pharmacy and the diversion investigation unit shall establish and maintain a program for the monitoring of prescribing and dispensing of all Schedule II, III, IV and V controlled substances and additional drugs identified by the board and the diversion investigation unit as demonstrating a potential for abuse by all professionals licensed to prescribe or dispense such substances in Tennessee.

(2) The requirements of this section shall not apply to the dispensing of controlled substances to inpatients in a hospital or long term facility or at the time of discharge from the hospital or facility.

(3) Each dispenser shall submit to the board of pharmacy and the diversion investigation unit by electronic means information regarding each prescription dispensed for a drug included under subdivision (b)(1). The information submitted for each prescription shall include, but not be limited to:

(A) Pharmacy prescription number;

(B) Pharmacy number (NABP);

(C) Patient identifier including name and one (1) of the following:

(i) Driver's license number;

(ii) Social security number; or

(iii) Tennessee ID number;

(D) Patient address;

(E) Patient date of birth;

(F) Prescription is new or is a refill;

(G) National drug code (NDC) of controlled substance dispensed:

(H) Metric quantity of controlled substance dispensed;

(I) Estimated days supply of controlled substance dispensed;

(J) Practitioner's U.S. drug enforcement administration (DEA) registration number;

(K) Practitioner's license number;

(L) Date prescription issued by practitioner;

(M) Date the controlled substance is dispensed;

(N) Name of person who receives the prescription from the dispenser, if other than the patient and one (1) of the following:

(i) Driver's license number;

(ii) Social security number; or

(iii) Tennessee ID number;

(O) Source of payment for prescription; and

(P) State-issued serial number corresponding to official Tennessee prescription form.

(4) Each dispenser shall submit the information in accordance with transmission methods and frequency promulgated by the board of pharmacy and the diversion investigation unit but shall report at least every thirty (30) days before the 15th of the month following the month the prescription was dispensed. The board of pharmacy shall coordinate information received from the reporting required by this part with any reporting required by part 3 of this chapter.

(5) The board of pharmacy and the diversion investigation unit may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information

by other means promulgated by the board of pharmacy, provided all information required in subdivision (b)(3) is submitted in this alternative format.

(c)

(1) Persons registered to manufacture, distribute, dispense, or possess controlled substances shall keep records and maintain inventories in conformance with the record-keeping and inventory requirements of the federal Comprehensive Drug Prevention and Control Act of 1970 or as amended, and the federal Food Drug and Cosmetic Act, and with any additional rules or regulations promulgated by the board of pharmacy.

(2) Any practitioner or dispenser shall keep for at least two (2) years from the date of preparation, every report, inventory, and record regarding the procuring, use, storage and dispensing for all drugs included under subdivision (b)(1).

(d)

(1) Prescription information submitted to the board of pharmacy and the diversion investigation unit shall be confidential and not subject to public or open records laws. except as provided in subdivisions (d)(3), (4) and (5).

(2) The board of pharmacy and the diversion investigation unit shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained is not disclosed to persons except as in subdivisions (d)(3), (4) and (5).

(3) The board of pharmacy and the diversion investigation unit shall review the prescription monitoring information. If there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the board of pharmacy or the diversion investigation unit shall notify the appropriate law

enforcement or professional licensing, certification or regulatory agency or entity, and provide prescription information required for an investigation.

(4) The board of pharmacy and the diversion investigation unit shall be authorized to provide data in the prescription monitoring program to the following persons:

(A) Persons authorized to prescribe or dispense controlled substances, for the purpose of providing medical or pharmaceutical care for their patients;

(B) An individual who requests the individual's own prescription monitoring information in accordance with procedures established under § 53-10-306(d)(1);

(C) Persons authorized to act on behalf of state boards and regulatory agencies that supervise or regulate a profession that is authorized to prescribe controlled substances, including but not limited to the following:

(i) Board of pharmacy;

(ii) Board of nursing;

(iii) Board of medical examiners;

(iv) Board of registration in veterinary medicine; and

(v) Board of registration in dentistry;

(D) Local, state and federal law enforcement or prosecutorial officials working with the diversion investigation unit engaged in the administration, investigation or enforcement of the laws governing prescription drugs;

(E) Personnel of the bureau of TennCare regarding Medicaid program recipients;

(F) Personnel of the United States Attorney, attorney general and reporter or the district attorneys general under subpoena or court order; and

(G) Personnel of the board of pharmacy or the Tennessee highway patrol for purposes of administration and enforcement.

(5) The board of pharmacy or the diversion investigation unit may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identity individual patients or persons who received prescriptions from dispensers.

(e) The board of pharmacy and the diversion investigation unit are authorized to contract with another agency of this state or with a private vendor, as necessary, to ensure the effective operation of the prescription monitoring program. Any contractor shall be bound to comply with the provisions regarding confidentiality of prescription information in § 53-10-306 and shall be subject to the penalties specified in subsection (h).

(f) The board of pharmacy and the diversion investigation unit shall promulgate rules and regulations setting forth the procedures and methods for implementing this act in accordance with the provisions of the Uniform Administrative Procedures Act, compiled in title 4, chapter 5.

(g) The board of pharmacy in conjunction with the head of the diversion investigation unit of the Tennessee bureau of investigation shall issue an annual report on the effectiveness of the prescription monitoring program.

(h) A violation of this section is a Class E felony. A second or subsequent violation of this section is a Class D felony.

53-10-402.

(a)

(1) The board of pharmacy shall designate an official Tennessee prescription form. The form shall be serialized and tamper-resistant. For the purposes of this section, “tamper-resistant” means unable to be altered, copied, or counterfeited. The board of pharmacy may contract with a private vendor to develop and print the official prescription form from a third-party vendor, provided the printer has met security regulations promulgated by the board.

(2) The official prescription forms shall be provided by the board of pharmacy or by the private vendor to registered practitioners and facilities without charge. Each series of prescriptions shall be issued to a specific practitioner in consecutively numbered blocks of fifty (50) and shall only be used by that practitioner. The board shall establish security regulations for the department and the private vendor concerning the procurement of the official prescription forms.

(3) A practitioner authorized to write a prescription in the state shall issue all written prescriptions upon an official prescription form. A pharmacist shall not fill a written prescription from a Tennessee practitioner unless issued upon an official prescription form. Nothing in this section shall be construed to impact regulations regarding oral, electronic, or out-of-state prescription practices.

(4)(A) A practitioner or facility shall register with the board of pharmacy in order to be issued official prescription forms. Registration shall be without charge. Registration shall include, but not be limited to:

(i) The name of a practitioner authorized to prescribe controlled substances;

(ii) The primary address and the address of additional places of business and;

(iii) The practitioner's drug enforcement agency number; and

(iv) The practitioner's license number.

(B) A practitioner's or facility's registration shall be subject to approval by the board of pharmacy, pursuant to rules promulgated by the board. Any change to a practitioner's or a facility's registered information shall be promptly reported to the board of pharmacy in a manner promulgated by the board.

(5)(A) A registered facility shall obtain official Tennessee prescription forms for use at the facility and shall assign the forms to registered staff practitioners. The number of official prescription forms issued to a registered practitioner or facility, by the board of pharmacy or the private vendor, shall be a reasonable quantity and at the discretion of the board. Official prescription forms shall be imprinted with:

(i) The name of the registered practitioner or the registered practitioners at a registered facility;

(ii) The registered practitioner's drug enforcement agency's identification number;

(iii) The primary address and the address of additional places of business; and

(D) The practitioner's license number.

(B) An official prescription form is not transferable and shall be used only by the registered practitioner or facility to whom issued.

(6) A registered practitioner or facility shall undertake adequate safeguards and security measures promulgated by the board to assure against destruction,

theft, or unauthorized use of an official prescription form. A registered practitioner shall, at minimum, maintain a record of official prescription forms received and establish a system requiring forms be secure pursuant to security measures promulgated by the board. A registered facility shall, at minimum, maintain a record of official prescription forms received, maintain a record of forms assigned to its registered staff practitioners, establish a system requiring forms be secure pursuant to security measures promulgated by the board and require a registered staff practitioner to surrender their assigned forms when the practitioner terminates affiliation with the registered facility.

(7) A registered practitioner or facility shall immediately notify the board of pharmacy, in a mariner promulgated by the board, upon their knowledge of the loss, destruction, theft or unauthorized use of an official prescription form. A registered practitioner or facility shall report the failure to receive official prescription forms to the board of pharmacy within a reasonable time after ordering the forms. A registered practitioner or facility shall immediately notify the department and the diversion investigation unit of the Tennessee bureau of investigation upon their knowledge of prescription diversion or suspected diversion pursuant to the loss, theft, or unauthorized use of an official prescription form.

(8) A violation of this section is a Class E felony. A second or subsequent violation of this section is a Class D felony.

(b) The board in conjunction with the head of the diversion investigation unit of the Tennessee bureau of investigation shall issue an annual report on the effectiveness the official Tennessee prescription form.

SECTION 2. Tennessee Code Annotated, Title 38, Chapter 6, is amended by adding the following as a new section:

38-6-121. There is established in the bureau of investigation a diversion investigation unit in order to investigate diversion of prescription drugs and to implement aspects of title 53, chapter 10, part 4.

SECTION 3. The board of pharmacy and the diversion investigation unit shall report to the general assembly on the status of this act six (6) months after passage. 53-10-402 shall take effect no later than January 31, 2010

SECTION 4. Section 1 shall take effect July 1, 2008, and all other provisions of this act shall take effect July 1, 2007, the public welfare requiring it.